

Theranexus: Inclusion of the first subjects in the efficacy study on the treatment of sleep disorders, in partnership with the French Armed Forces Biomedical Research Institute (IRBA)

Paris, 19th October 2015 – Biotechnology company Theranexus—founded by Franck Mouthon, CEO, and Mathieu Charvériat, Scientific Director—is pleased to announce the launch of the clinical efficacy phase of its lead program, THN102, in the treatment of sleep disorders.

Based on the positive results obtained in phase I, which focused on the safety of THN102, Theranexus was granted authorisation to assess the efficacy of the product. Coordinated by IRBA's Fatigue and Vigilance unit headed by Mounir Chennaoui and backed by the French Army's Central Pharmacy for the manufacture and release of experimental medication, the Phase-Ib study is being conducted at the Percy Military Hospital (HIA) in Clamart near Paris. Head doctor, Fabien Sauvet, a sleep specialist from the IRBA, is managing the double-blind trial with placebo, active comparator and the product THN102 being administered in three doses to sleep-deprived volunteers. The trial is designed to assess the capacity of THN102, in particular, to keep subjects awake and maintaining their level of cognitive performance (attention, memory). The study has the financial backing of the French Defence Procurement and Technology Agency (DGA) in the framework of the government's "RAPID" program that supports defence-sector R&D projects.

As Mathieu Charvériat, Scientific Director of Theranexus, explains, "We are very pleased to see the first subjects included in this highly significant study. It will provide us with convincing evidence of the therapeutic benefits that THN102 will provide to subjects with sleep disorders. Even when administered the best treatments currently available, patients with sleep disorders such as narcolepsy and obstructive sleep apnoea regularly suffer from residual drowsiness. THN102 is expected to offer a solution for these patients."

Franck Mouthon, CEO of Theranexus, declares, "We are delighted to see the clinical development of the product progress according to schedule, with results expected in the first half of 2016. The DGA's support together with the expertise of the IRBA—renowned for the clinical trials it carries out in fatigue and vigilance—have played a decisive role in achieving this new milestone."

The trial will be followed by a phase-II study in patients with narcolepsy.

What are narcolepsy and sleep-wake disorders?

Narcolepsy is a rare disease. It is characterized by a chronic sleep disorder or rare dyssomnia, and also excessive daytime sleepiness: the individual feels extreme fatigue and can uncontrollably fall asleep at an unsuitable moment, at work, at school, in the street, etc.

The disease generally begins during adolescence and affects both sexes, but it can also appear later (around the age of 35). In France, an estimated 10,000 people are affected and over 500,000 are affected in the rest of the world. Some 60% to 70% of patients are currently receiving treatment that has proven insufficient, hence the need to find a new treatment to remedy this truly debilitating condition.

Other sleep-wake disorders include in particular sleep apnea or obstructive sleep apnea-hypopnea syndrome (OSAHS), a nocturnal breathing disorder characterized by abnormally frequent respiratory pauses. As this syndrome affects almost 4% of the population, it leads to excessive daytime sleepiness despite current treatment.



About Theranexus

Founded in 2013 by Franck Mouthon, CEO, and Mathieu Charvériat, Scientific Director, Theranexus is a biotechnology company designing and developing drug combinations to improve the efficacy and safety of certain neurological and psychiatric treatments.

Theranexus draws from an experienced Supervisory Board to guide it in its strategic choices and from a Scientific Council of medical and industrial experts for the company's main priorities.

In October 2014, Theranexus raised its first venture capital of €3.6 million from Auriga Partners, Sofimac Partners, CEA Investissement and Rhône-Alpes Création.

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